

## **PSJ2 Exh 42**



# 2004

## ACTIQ Marketing Plan



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## I. EXECUTIVE SUMMARY

### 2003 Performance Review

Cephalon experienced another extraordinarily successful year with ACTIQ in 2003. This achievement can be attributed primarily to focused and integrated marketing and sales efforts. Key indicators of the growing demand for ACTIQ include:

- 2003 projected TRx of 304,354 (64% growth over 2002)
- 2003 projected sales of at least \$240.0 MM (80% growth over 2002)
- ACTIQ quarterly prescriber count has grown an average of 14% quarter-over-quarter from Q3 2001 to Q2 2003
  - 45% growth among anesthesiologists/pain specialists prescriber base (key targeted physician segment) from MAT June 2002 (1498 prescribers) to MAT June 2003 (2166 prescribers)
- 35% increase in productivity among anesthesiologists/pain specialists from MAT June 2002 (39 TRx/prescriber) to MAT June 2003 (53 TRx/prescriber)
- 66% growth in market share among pure short-acting opioids from MAT June 2002 to MAT June 2003
  - 2% increase in TRx market share among pure short-acting opioids (both branded and generic) from MAT June 2002 (3% TRx market share) to MAT June 2003 (5% TRx market share)
  - ACTIQ was the *only* branded pure short-acting opioid to increase TRx market share over each of these time periods.

### 2004 Commercial Objectives

Based on the success of the current promotional platform, ACTIQ will continue to be positioned as fentanyl in a unique delivery system providing the most rapid onset of analgesia of any non-invasive opioid available. The commercial objectives for ACTIQ include the following:

- Achieve factory sales and TRx count targets
- Expand the ACTIQ prescriber base, especially among the most productive physician segments
- Increase productivity among targeted physician segments
- Develop and execute an effective publication plan, which will generate critical commercial information rapidly
- Drive the direction and development of phase IV research (produce data as rapidly as possible)

2003 ACTIQ Gross Sales & TRx Budgets			
	2002 Actual	2003 Budget	% Growth
Gross Sales	\$240.0 MM	\$354.4 MM	48%
TRx	304,354	435,419	43%

#### **2004 Key Marketing Issues**

The key marketing issues facing ACTIQ in 2004 are as follows:

- Low awareness in the assessment and treatment of BTP
- Low product awareness among patients and prescribers
- Limited number of key opinion leaders/advocates
- Limited clinical data and publications
- Potential branded competitors in 2005
- Physician fear/concern of prescribing opioids ("Opiophobia")
- Combining of sales forces: potential loss of focus on ACTIQ
- Potential negative reaction to new compressed powder formulation

#### **2004 Marketing Strategy**

The overall marketing strategy for 2004 will continue to build on the successful platform developed in previous years, which will be to 1) raise awareness of BTP and ACTIQ through PR and marketing driven awareness initiatives and 2) differentiate ACTIQ from its competitors by educating clinicians about the core product benefits (rapid onset of analgesia, portability, convenience and patient controlled administration) through targeted medical education initiatives. Ideally, this will drive physicians along the product adoption curve from awareness and trial to usage and adoption. Specific marketing strategies have been developed for each key issue listed above.

#### **2004 Tactical Summary**

ACTIQ marketing strategies will be executed through a variety of tactical initiatives that convey ACTIQ key messages and differentiate ACTIQ from its competitors based on its primary patient benefits. As in 2003, the majority of tactics will focus on education and awareness in 2004. Initiatives focused on improving awareness of BTP and ACTIQ will be utilized among both patient populations and clinicians. Both promotional and continuing medical education programs will be implemented in 2004 and continue to comprise the most critical component of the tactical plan.

## II. SITUATION ANALYSIS

### A. 2003 REVIEW

#### *2003 Marketing Strategy Review*

The primary 2003 ACTIQ marketing strategy was to continue differentiating ACTIQ from its competitors by highlighting the primary product benefit, rapid onset of pain relief. This strategy has not changed over the last several years and will again be the central focus in 2004. Supporting strategies directly addressed each of the key marketing issues identified for 2003.

#### **2003 Promotional Strategies**

- Strengthen the association of ACTIQ and its key patient benefits through improved awareness and medical education
- Educate key targeted physician specialties about the importance of assessing BTCP and the benefits of treating it with ACTIQ
- Enhanced medical meeting presence to raise awareness/lack of branding of ACTIQ/Cephalon within the pain community
- Proactively inform all target audiences of the impending transition to the compressed powder formulation
- Build/renew relationships with KOLs in pain management and targeted physician specialties through consultant meetings and advisory boards.
- If adequate clinical support provided, drive the direction of phase IV research and publication efforts to be consistent with commercial needs
- Proactively position ACTIQ to defend its market share against potential competition
- Direct the most effective promotional efforts to the highest potential targeted physicians

Overall, the marketing strategies implemented in 2003 have proven exceptionally effective, but not all of the strategies listed above have been executed. For example, phase IV research has yet to be initiated due to a lack of medical support for ACTIQ, as well as a delay in strategic decision making regarding ACTIQ and potential future pain products. Nonetheless, factory sales and total prescriptions are projected to exceed initial 2003 targets.

#### *Objectives for 2003 included the following:*

- Achieve factory sales and total prescription (TRx) count targets
- Increase the number of ACTIQ prescribers, especially among the most productive physician specialties and key physician segments
- Increase the productivity among targeted physician specialties and deciling segments
  - Move prescribers along the product adoption curve (from dabblers to users) and increase the number of prescribers in the top five prescribing deciles

- Continue developing/renewing relationships with key opinion leaders and influencers
- Establish a plan of action and begin implementation for positioning ACTIQ against future branded competition

## B. SALES AND PRESCRIPTION UPDATE

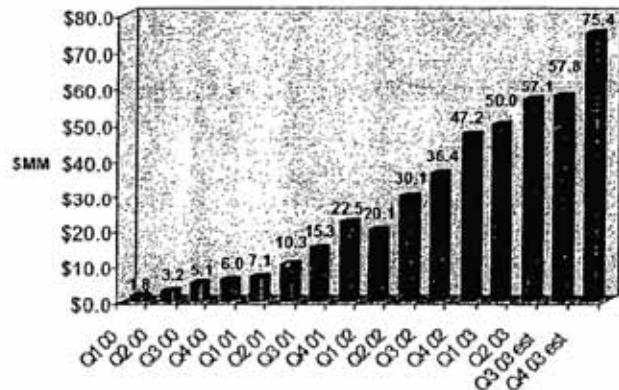
### *Factory Sales Since Launch*

ACTIQ factory sales grew modestly through the first two years following launch in April 1999. The product suffered through two distinct, ineffective and under-supported launches (Abbott Laboratories April 1999; Anesta Corp. May 2000). Cephalon's re-launch of ACTIQ in March 2001 represented a critical upgrade in the quality of sales force and marketing personnel, as well as resources applied to both promotion and education. An immediate and direct correlation can be made with the Cephalon 2001 re-launch of ACTIQ and the sudden change in the factory sales growth trend observed.

### *2003 ACTIQ Factory Sales*

ACTIQ factory sales continued to grow at an extraordinary pace in 2003 due to continued effective promotional and educational efforts. Achieving a projected factory sales total of \$240.0 MM will result in eclipsing the budget of \$227.0 MM which would represent growth of 73% over the sales of \$133.8 MM in 2002.

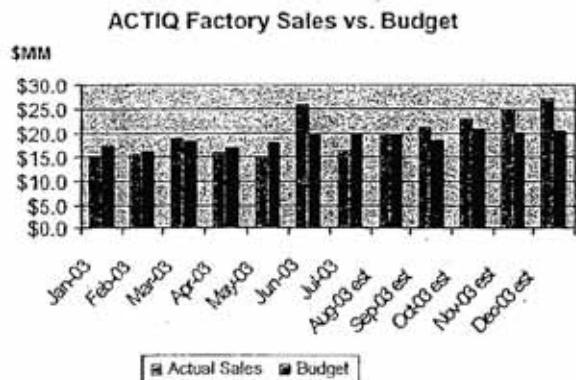
ACTIQ Factory Sales by Quarter



Source: DDN

### *2003 ACTIQ Factory Sales Versus Budget/Forecast*

ACTIQ factory sales are on target to reach \$240 MM in 2003 and exceed budget by 6%. The changeover to the new compressed powder formulation of ACTIQ occurred mid-year. In an effort to manage the transition, all of the old formulation was shipped out of the distribution center (DDN) in June causing the spike in June sales.



Source: DDN

#### *Sales Distribution Channel Mix*

Year-to-date 2003 sales distribution amongst demand channels is seen below. Because ACTIQ is ideally utilized as an outpatient pain medication, it is no surprise that retail (94%) and mail order (1%) demand sales dollars combine to account for 95% of demand sales.

	January – June 2003	% of Sales
<b>Total Demand Sales</b>	\$11,524,462	100%
Retail	\$10,697,692,115	94%
Non-Retail	\$327,724,89	5%
Mail Order	\$359,060,105	1%

Source: IMS NPA

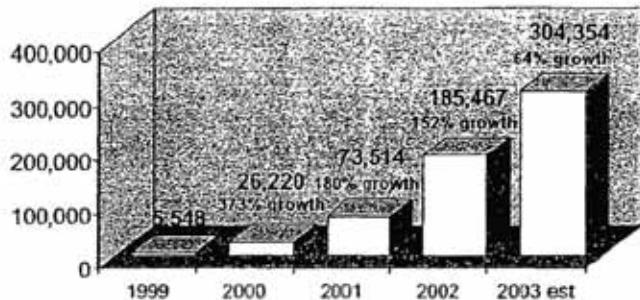
#### *ACTIQ Total Prescriptions Since Launch & Versus Forecast*

Since launch, ACTIQ prescriptions have realized tremendous growth. The total number of prescriptions (TRx) written since product launch in April 1999 exceeded 350,000 through March 2003.

For 2003, achieving the projected total prescription count of 304,480 will result in falling short of the forecast of 320,032, despite growing 64% over the total prescription count of 185,467 in 2002. The reason for the shortfall is that a lower cost per prescription was used to calculate the forecast and thus, when the forecast was created, a higher volume of lower cost prescriptions was needed to meet the sales expectation. Since the cost per prescription rose significantly from 2002 to 2003, the reality is that fewer prescriptions

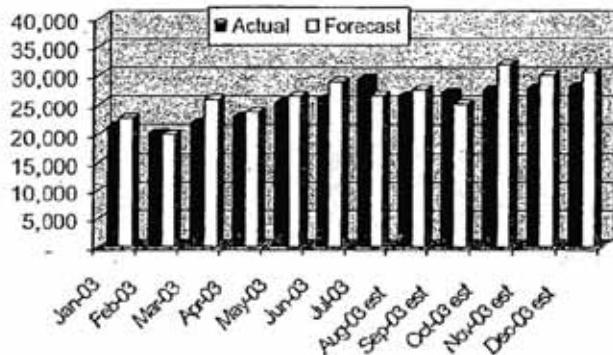
are now needed to achieve the sales goal. This significant acceleration in growth of prescriptions is due primarily to more focused promotional and educational efforts.

**ACTIQ Year on Year Prescription Growth**



Source: IMS NPA

**ACTIQ Prescriptions vs. Forecast**



Source: IMS NPA

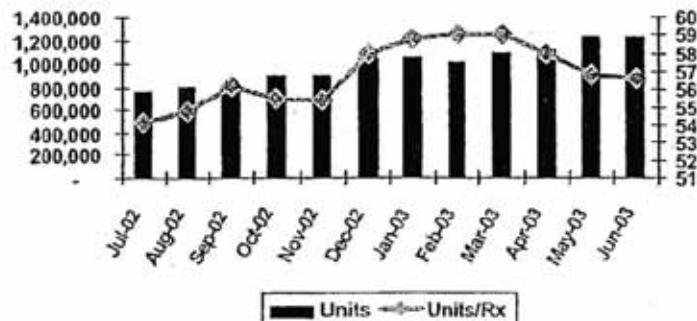
#### **Units and Units Per Prescription**

Total unit volume for ACTIQ has grown from an average of 722,599 units prescribed per month in 2002 to over 1.1 million units per month in the first part of 2003. Increases in the number of small prescriptions for titration and new patient starts, as well as increases in larger prescriptions for maintenance contributed to this increased total unit volume.

Additionally, units/Rx in the first half of 2003 have averaged 58, higher than the average of 54 units/Rx in 2002. This is evidence that many physicians continue to become more comfortable with ACTIQ and have moved toward the usage and adoption end of the product adoption curve and have thus become more productive prescribers.

The growth in the number of both large and small prescriptions along with the growth in units/Rx demonstrates that ACTIQ continues to expand with new patients while remaining a maintenance therapy for many others as physicians have adopted it into their practice.

#### Total Units & Units/Rx Analysis

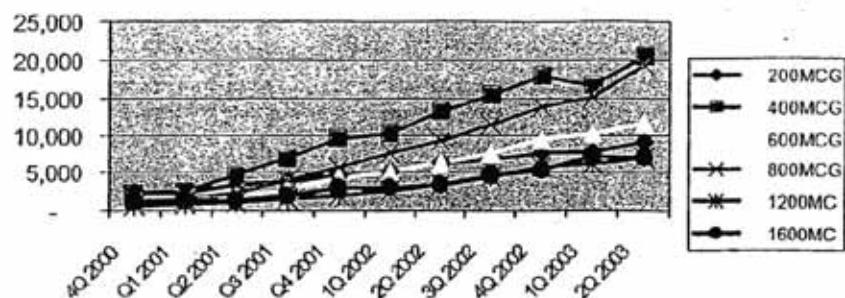


Source: NDC Source Prescriber

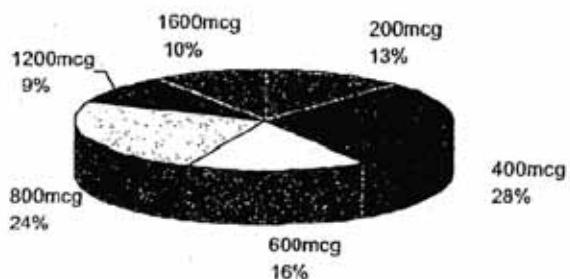
#### *Prescription Count by Strength*

For the time period MAT June 2002, the 400mcg and 800mcg strength prescriptions accounted for 32% and 21% respectively and comprised the two largest percentages of prescriptions written across all strengths. Through the first half of 2003, the 400mcg and 800mcg strength prescriptions again comprise the two largest percentages of prescriptions at 28% and 24% respectively. The 400mcg strength at 28% continues to account for more than double the prescriptions of the 200mcg strength at 13%. The evolution away from the 200mcg strength can be primarily attributed to improved education regarding dosing and titration and a much broader prescribing base. This transition, from depending so heavily on the 200mcg strength as the starting point, was another critical step in the evolution of ACTIQ. Fewer prescriptions at the 200mcg strength meant fewer patient failures/more patient successes, greater physician satisfaction and ultimately, greater and continued product use. Again, this transition is another significant indicator that many current ACTIQ prescribers have moved along the product adoption curve towards usage and adoption.

ACTIQ Quarterly TRx by Strength



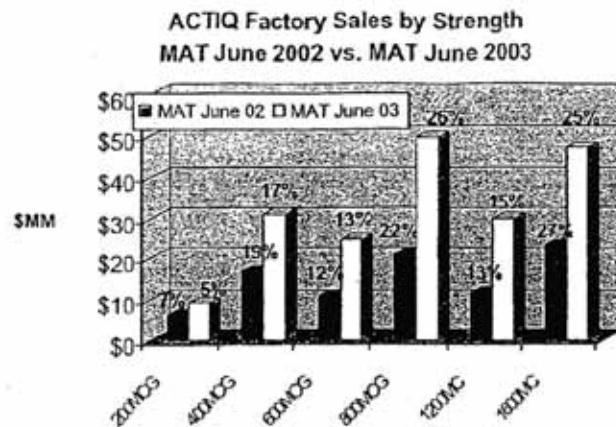
Source: IMS NPA

ACTIQ Rx Distribution by Strengths  
MAT June 2003

Source: IMS NPA

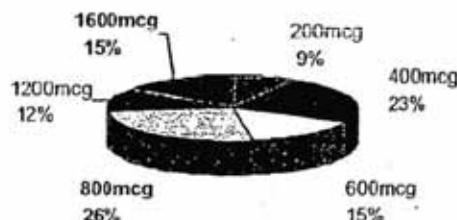
**Sales by Strength**

The 800mcg (26%) and the 1600mcg (25%) strengths account for the majority of total factory sales for the time period MAT April 2003. The 800mcg strength represents the average strength prescribed and accounts for the highest percentage (26%) of the total units, thus driving up its proportion of sales. The 1600mcg only represents 15% of the units prescribed, however it is the highest priced strength so it represents a high proportion of sales.



Source: DDN

**ACTIQ Units Distribution by Strength  
MAT June 03**



Source: IMS NPA

### C. PRESCRIBER BASE ANALYSIS

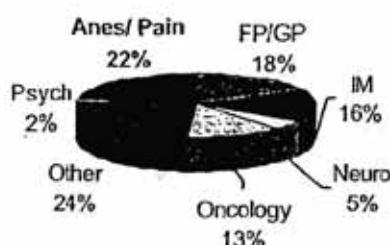
#### *Total and Quarterly Prescriber Count*

The total ACTIQ prescriber count for MAT June 2003 was 9,749. Pain specialists have been the focus of key promotional and educational marketing and sales initiatives throughout 2003 and continue to comprise the largest single specialty segment of the ACTIQ prescribing base at 22% for MAT June 2003. The segment labeled "Other" is comprised of many varied specialties writing small amounts of ACTIQ.

#### ACTIQ Percentage of Prescribers by Specialty

MAT June 2003

(Total prescribers = 9,749)

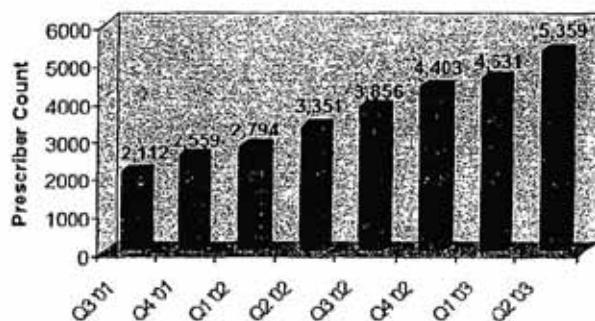


Source: NDC Source Prescriber

The ACTIQ prescriber count has grown an average of 14% quarter-over-quarter from Q3 2001 to Q2 2003. This continued growth in the number of ACTIQ prescribers demonstrates the continued effectiveness of education and awareness programs along with sales force efforts in 2003.

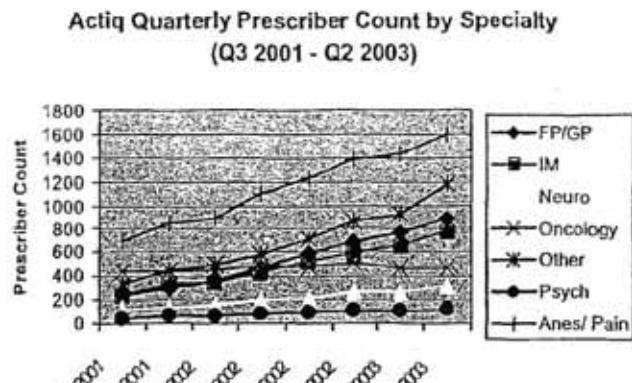
#### Actiq Quarterly Prescriber Count

(Q3 2001 - Q2 2003)



Source: NDC Source Prescriber

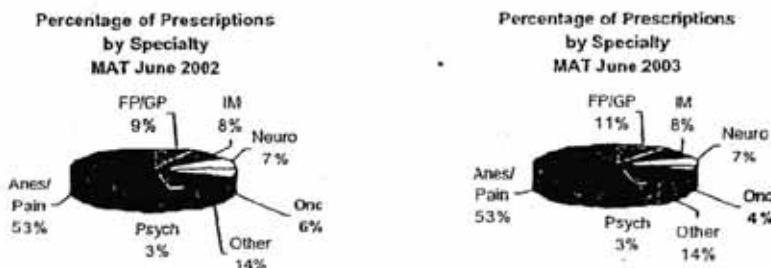
Examination of prescriber count by specialty over this same time period shows the most growth continues among pain specialists.



Source: NDC Source Prescriber

**Total Prescriptions and Productivity by Physician Specialty**

Pain specialists wrote the majority of prescriptions at 113,810 TRx for MAT June 2003, which was a growth of 95% over the previous period. Conversely, oncologists wrote only 7,471 total prescriptions, which represented just 4% of all prescriptions. In addition, oncology prescriptions grew just 11% while other key specialties had prescription growth of 83% or higher over the previous time period. This can somewhat be attributed to the fact that Cephalon has, in addition to focusing on oncology, focused marketing and selling efforts on pain specialists and those skilled in the use of opioids (prescribing segments often much more receptive to ACTIQ messaging). Historically, oncologists have been less receptive to ACTIQ messaging as disease management is their primary focus.



Source: NDC Source Prescriber

**Productivity by Physician Specialty**

An increase in total prescriptions was seen in all physician specialties from MAT June 2002 to MAT June 2003. Pain specialists continue to be the strongest advocates and the

most productive segment of our prescribing base (53 TRx/prescriber). Despite the fact that the total prescriptions from the oncology segment did increase from MAT June 2002 to MAT June 2003 by 11%, this was the smallest increase among all specialties and they remain our least productive segment, contributing only 6 TRx/prescriber over each of the time periods evaluated (no increase from MAT June 2002 to MAT June 2003).

#### Productivity by Physician Specialty

Specialty	MAT June 2002			MAT June 2003		
	TRx Count	TRx per Prescriber	Units per TRx	TRx Count	TRx per Prescriber	Units per TRx
Anes/ Pain	53,249	39	5.7	113,810	53	5.7
FP/GP	10,563	11	5.1	21,215	13	5.1
IM	14,822	10	4.9	27,215	11	4.9
Neuro	7,518	28	1.1	17,863	30	1.1
Oncology	6,604	6	4.1	7,413	6	4.1
Psych	13,104	28	1.1	15,143	26	1.1
Other	14,634	12	3.2	29,470	12	3.2
<b>Total</b>	<b>109,890</b>	<b>18</b>	<b>5.2</b>	<b>210,335</b>	<b>22</b>	<b>5.2</b>

Source: NDC

Further analysis of the Anes/Pain segment, the most productive prescribing segment follows.

#### Prescription Analysis of Pain Specialists

	MAT June 2002			MAT June 2003		
	TRx Count	Physician Count	Avg TRx/Physician	TRx Count	Physician Count	Avg TRx/Physician
Anes/ Pain	58,249	1,498	38.88	113,810	2,166	52.54
<b>% Growth from MAT June 2002</b>				95%	45%	35%

Source: NDC Source Prescriber

A target audience analysis will be presented later, however, it is interesting to note that effective physician targeting continues to be critical to our success with ACTIQ. The focused targeting directive implemented upon the Cephalon re-launch in 2001 was maintained in 2002 and only slightly modified in 2003. Sales and marketing targets include oncologists, pain specialists and selected other physicians skilled in the use of opioids.

#### D. USAGE BY DISEASE AREA

##### *Limitation of Resources*

The current data source utilized at Cephalon for disease usage information is captured in the Physician Drug and Diagnosis Audit (PDDA) from Scott Levin. This audit does not include anesthesiologists, which represent the largest and most productive segment of the ACTIQ prescriber base. Scott Levin does include oncologists and neurologists in the PDDA audit, however, the data are limited because of ACTIQ's small prescription base. As a general rule when analyzing PDDA data, anything below 100,000 uses should be viewed only directionally.

PDDA reported approximately 60,000 total projected uses of ACTIQ during MAT March 2003, with over three-quarters of the uses in pain and malignancies. Based on the limitations of PDDA for ACTIQ, this data source may not adequately report a realistic representation of disease specific usage of ACTIQ.

MAT March 2003		
	Actiq use	%
Headache	13,000	22%
Pain	36,000	60%
Malignancies	8,000	13%
Total	60,000	100%

Source: Scott Levin PDDA

##### *Usage Study*

Because of the limitations of PDDA, primary research was conducted to determine actual usage of ACTIQ. During August and September 2002, IMS Health recruited 82 physicians to report on their most recent 1-10 patients who were treated with ACTIQ in the previous 90 days. The physicians were from various specialties (37% were anesthesiologists/pain management; 22% physical medicine and rehab; 21% primary care; 20% other) and were a representative sample of deciles 3-10 of our total prescribing base. See table below for the breakdown.

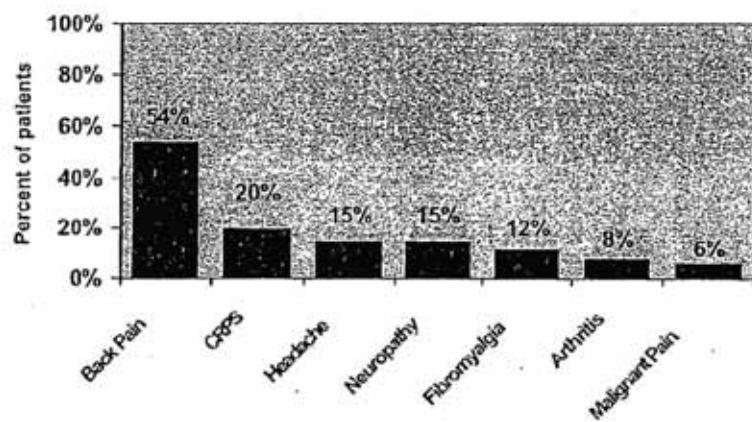
	Total Population		
	Sample Size	Available Physician Count	Actiq TRX Range for Jan - Jun 2002
Deciles 3-5	10	50	15-19
Deciles 6-8	16	155	170-219
Deciles 9-10	6	34	220-340
Total	82	743	

Source:

The results incorporated 616 patients in the final sample. The data were projected to national levels by using a proprietary IMS projection methodology that marries the universe of ACTIQ prescribers (Xponent® data provided by Cephalon) with the physician and patient-level data provided by physicians (the ACTIQ survey booklet). The projection estimates the proportion of ACTIQ patients that are being treated for each underlying condition overall.

Based on physician reporting, 54% of the patients were prescribed ACTIQ for chronic back pain. This suggests that once physicians understand the product, they continue to apply ACTIQ to a broader group of pain patients. The ACTIQ business strategy team has continued to discuss negotiation efforts with FDA to expand the indication to allow for appropriate promotion to physicians utilizing ACTIQ in these areas.

**Distribution of Conditions Treated with ACTIQ  
(Projected)**



Source: physician surveys and IMS Xponent audit

## E. TARGET AUDIENCE ANALYSIS

### *Target Audience*

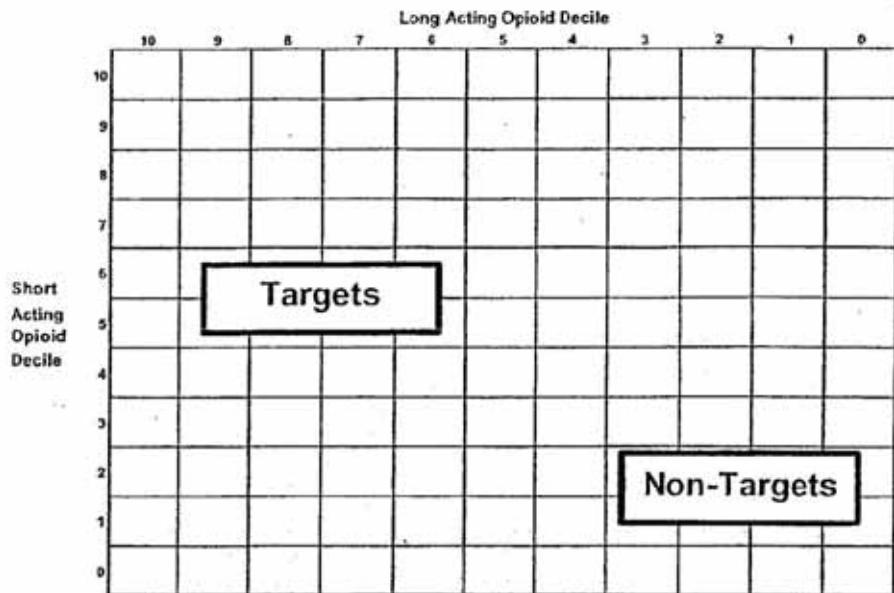
The ACTIQ target audience includes oncologists, pain specialists and selected physicians skilled in the use of opioids. Success with ACTIQ to date has been achieved through 1) focused promotional and selling efforts dedicated and targeted to physicians who are highly skilled in the use of opioids and 2) the creation of a solid, core group of prescribers. As observed in 2003, continued success will be achieved through the maintenance and expansion of this core group of prescribers. Therefore, it is critical for marketing and sales to identify the prescribers that have the greatest potential to fall within this core group of physicians.

The following table shows the targets based on the expected 2004 sales force structure and their capacity for reach with desired frequency. General surgery, pediatricians and dentists are excluded due to the contraindications for ACTIQ.

	275 reps 13,094 prescribers	450 reps 26,201 prescribers
<b>ACTIQ decile</b>		
Long acting opioid decile		
Short acting opioid decile		
Long acting opioid decile & Short acting opioid decile		
Short acting opioid decile & Long acting opioid decile		
Duragesic decile		
<b>Total opioid decile</b>		

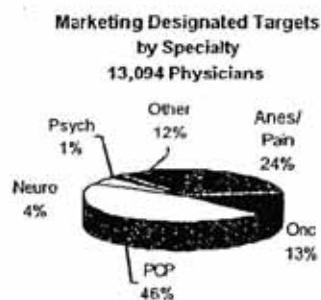
The chart below illustrates the ACTIQ targets based on long and short acting opioids according to the criteria described above.

**ACTIQ Targets Based on 275 Sales Representatives  
13,094 Prescribers**

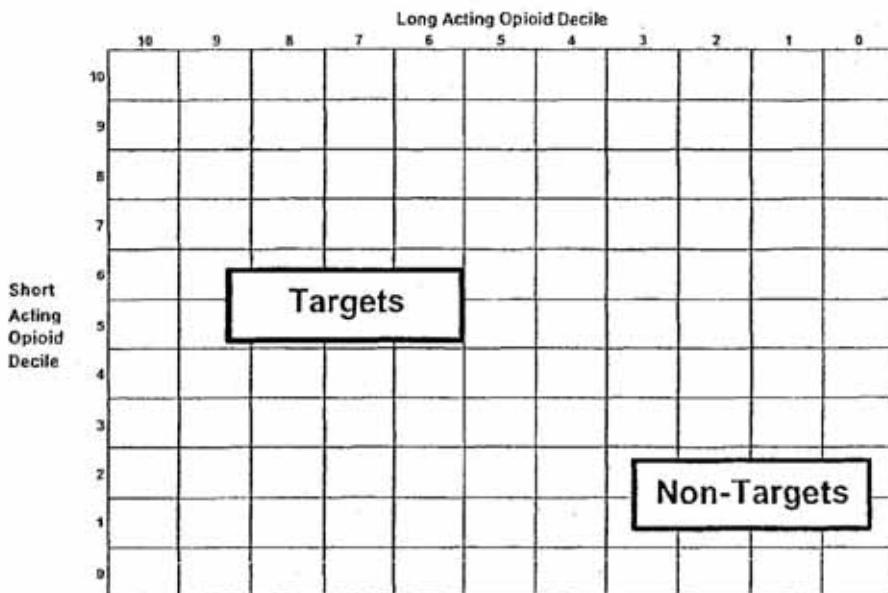


The targets for 275 representatives break down into the following specialty segments:

Specialty Group	Prescribed Count
Anes/Pain	3,084
Onc	1,669
PCP	6,129
Neuro	506
Psych	169
Other	1,537
<b>Total</b>	<b>13,094</b>



**ACTIQ Targets Based on 450 Sales Representatives  
26,201 Prescribers**



The targets for 450 representatives break down into the following specialty segments:

Specialty Group	Prescriber Count
Anes/Pain	4,019
Onc	2,841
PCP	14,516
Neuro	884
Psych	266
Other	3,675
<b>Total</b>	<b>26,201</b>



***Target Market Penetration***

Currently, we have very low penetration of the 26,201 marketing designated sales targets. Only 4,277 physicians (16%) of the 26,201 targets have prescribed ACTIQ to date in 2003. Of the 4,019 pain specialists among these 26,201 targets, 1,653 (41%) have prescribed ACTIQ to date in 2003. This moderate penetration of a key physician segment represents a tremendous opportunity for continued growth.

Total Targets			
Specialty Group	Prescriber Count	ACTIQ Prescribers	ACTIQ Prescribers as a % of Target
Anes/Pain	4,019	1,653	41%
Onc	2,841	447	16%
PCP	14,516	1,257	9%
Neuro	884	287	32%
Psych	266	89	33%
Other	3,675	544	15%
Total	26,201	4,277	16%

#### *Market Segmentation Needs*

Based on feedback from physicians at advisory panel meetings and consultant meetings held in 2003, it appears that there is a need to perform some analysis to further segment physicians. Physicians cited use of ACTIQ in a multitude of pain types during these meetings and encouraged Cephalon to pursue research in these areas. These opinions came from physicians across a variety of specialties, however, it was obvious that certain physicians treat pain differently than others; there are different philosophies in treating certain types of pain. In order to better understand our market, it will be critical to perform an analysis of specific segments of the ACTIQ target universe to determine which physicians are potentially sensitive to particular ACTIQ messages. This will help us focus certain 2004 marketing specific tactics toward the correct market segment. This market segmentation analysis will be conducted in the second half of 2003.

#### *Pain Care Specialist Call Activity*

Pain Care Specialists averaged 4.5 calls/day for July 2002 through June 2003, up from 4.3 calls/day from the 2003 Marketing Plan. This represents approximately 92,000 target physician interactions among 10,099 physicians. This slight increase in call frequency is most likely due to the geographical size reduction of some of the PCS sales territories from the expansion from 60 to 79 PCS sales representatives. Combining and expanding the PCS and CNS sales forces will shrink sales territories dramatically, expand our direct promotional reach and, hopefully provide for increased frequency with key designated targets. Because ACTIQ is a time intensive sale, frequency cannot be sacrificed for expanded reach.

#### *ACTIQ Prescriber Decile Analysis*

Analysis of the top five ACTIQ prescribing deciles MAT April 2002 versus MAT April 2003 highlights two key findings.

### ACTIQ Decile Analysis

Actiq Decile Summary MAT June 2002			Actiq Decile Summary MAT June 2003		
Specialty Group	Physician Count in Top 5 Deciles	% of Top 5 Deciles	Specialty Group	Physician Count in Top 5 Deciles	% of Top 5 Deciles
Anes/Pain	127	61%	Anes/Pain	191	65%
Other	23	14%	Other	30	12%
Neuro	21	7%	FP/GP	25	9%
IM	13	6%	Neuro	23	6%
FP/GP	15	7%	IM	21	6%
Oncology	3	1%	Psych	8	2%
Psych	6	4%	Oncology	2	1%
Total	208	100%	Total	300	100%

Source: NDC

First, the number of physicians within the top five prescribing deciles has increased 44% from MAT June 2002 (208 prescribers) to MAT June 2003 (300 prescribers). Continued growth in the number of physicians prescribing half of all ACTIQ prescriptions is important because it expands the number of prescribers on whom we rely.

The second key finding is the continued dominance of pain specialists among the top ACTIQ prescribers. Pain specialists comprised 61% of the prescribers (127 of 208) among the top five deciles over the time period MAT June 2002 and increased to 65% (191 of 300) over the time period MAT June 2003.

Also interesting, although not shown, is the fact that the number of decile 1 and 2 physicians for MAT June 2002 was 5,145 and increased 64% to 8,447 for MAT June 2003. So, in addition to the significant growth (44%) among users and adopters (i.e. physicians in the top five deciles), there was also tremendous growth (64%) among physicians in the first stages of the adoption curve (awareness and trial).

### ACTIQ Prescriber Decile – Product Adoption Curve Analysis

Product Adoption Curve Stages	Prescriber Count MAT June 2002	Prescriber Count MAT June 2003	Growth
Adoption (Deciles 8-10)	71	110	55%
Usage (Deciles 5-7)	263	371	41%
Trial & Awareness (Deciles 1-4)	5,706	9,268	62%
<b>TOTAL</b>	<b>6,040</b>	<b>9,749</b>	<b>61%</b>

#### F. PRODUCT AWARENESS AND PERCEPTION

Market research is currently underway which when completed will allow the ACTIQ marketing team to better understand the perception and current awareness of ACTIQ. This research will be completed in late Q3 2003.

#### G. REIMBURSEMENT UPDATE

##### *Reimbursement Overview*

ACTIQ generally continues to operate under the radar screen of most managed care organizations, though there has been an increase in the implementation of restrictive measures in an attempt to limit access. Despite this increase, the majority of prescriptions continue to be reimbursed for malignant as well as non-malignant pain patients. The formulary status of ACTIQ is not a critical factor in determining the success of the product in the market. The critical marker is the reimbursement status of ACTIQ. Though ACTIQ continues to occupy a positive formulary position with several managed care organizations, the majority of plans classify the product as a non-formulary reimbursed drug. This status is often reserved for low volume specialty products or those branded products that have a cost disadvantage and/or lack of differentiation. In these plans there has generally been a limited effort to restrict access through prior authorization.

State Medicaid programs have increasingly been subject to state budgetary pressures and have therefore been moving toward preferred drug lists, prior authorization and supplemental rebate programs. ACTIQ has been put under prior authorization in several states over the course of the last several months with anticipation that that trend will continue. Currently, 13 states have ACTIQ under a prior authorization with limited success in denying access to the product.

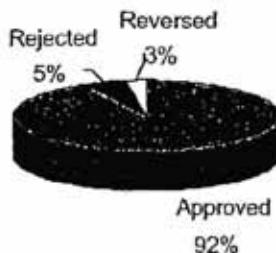
In a minority of plans where ACTIQ formerly held a positive reimbursement or formulary position, prior authorization or other restrictive measures have been put in place in an attempt to control utilization. The prior authorization often is comprised of one or more of the following:

- Approved within indication and requiring supporting clinical data for uses outside of BTCP
- One or two documented formulary agents used first
- Quantity Limits

In spite of the implementation of prior authorization within specific plans, with a few notable exceptions (i.e. BS CA, Regence), ACTIQ continues to perform in line with the overall 3<sup>rd</sup> party market. To provide an overall market perspective, a sample evaluation performed by Verispan over the time period of April 1, 2003 to June 30, 2003 tracked a

total of 1,619 ACTIQ prescriptions. The results showed that 92.3% of the prescriptions were approved, while only 5% were rejected.

**Percent of Claims Approved/Rejected/Reversed  
(4/01/03-6/30/03) 6,490 ACTIQ TRx**



Source: Verispan

Additionally, further investigation by Verispan demonstrated that 90% of all copays associated with ACTIQ prescriptions are for less than \$40.00.

<b>Out of Pocket Costs (OPC) Distribution* for Actiq</b>		
<b>COST RANGE</b>	<b>#</b>	<b>%</b>
\$0-\$10.00	396	24%
\$11-\$20.00	160	10%
\$21-\$30.00	123	8%
\$31-\$40.00	367	23%
\$41-\$50.00	406	25%
\$51-\$60.00	167	10%
<b>Total</b>	<b>1,619</b>	<b>100%</b>

\* OPC distribution is based on paid claims for focus drug Actiq for scripts with a days supply equal to the mode (30 days)

Note: The average out of pocket cost per day is \$1.23

***Actiq Reimbursement Hotline***

The following data represent data and trends obtained through the ACTIQ Reimbursement Hotline activity July 01, 2002 through June 2003.

**Reimbursement Hotline Activity**

Total number of cases handled and resolved (not pending)	24
Cases successfully resolved	75%
Appeal rate for previously denied claims	28% 17 cases pending appeal: 1 case each: Fibromyalgia, Dorsal Fractures, Degenerative Disc Disease, Crohn's Disease, Migraine headache, Neoplasm of unknown origin, Polycystic Kidney Disease
Percentage of covered claims with non-BTCP	83%
Most common non-BTCP diagnoses covered	Fibromyalgia and back pain
Percentage of plans covering ACTIQ requiring prior authorization	17% (66% non-BTCP diagnosis)
Percentage of plans covering ACTIQ utilizing tiered co-pays	28% (5 cases)
Percentage of plans covering ACTIQ utilizing step therapy	11% (2 cases)

**Trends:**

- Increasing number of patients utilizing ACTIQ reimbursement assistance for non-BTCP diagnoses
- Instances of Medicaid initially covering for non-BTCP diagnoses then subsequently denying
- Insurers setting dosage limits (i.e. 96/month)
- More restrictive Medicaid pharmacy benefits

As ACTIQ continues its tremendous growth and physicians grow comfortable utilizing ACTIQ in a variety of patients, it is anticipated and expected that MCO reimbursement issues will increase proportionally. Currently, there are several plans that have attempted to put restrictions in place with limited success. Though these plans are few in number they are large in scope (i.e. United) and it will become increasingly important to limit the negative perception that a few reimbursement issues may create in the physician's mind. In addition, it will also be important to continue to monitor the implementation of coinsurance in the managed care market considering that this is a member cost sharing tactic that has the potential to impact sales. Currently, there are only a few plans that have implemented this tactic. Finally, as the number of reimbursement issues expands it becomes increasingly important to address the lack of peer reviewed publications,

continue to investigate the pharmacoeconomic opportunity around ACTIQ and produce managed care materials to clinically address the lack of understanding around breakthrough pain and ACTIQ with select, restrictive organizations.

## H. MEDICAL EDUCATION AND PROMOTION RESPONSE

### *Continuing Medical Education*

CME played a vital role in the education of physicians, nurses and pharmacists in 2003 regarding BTP. The major CME initiatives in 2003 included a CME on-demand teleconference, local and regional CME symposia (*CEP Lectures*), a tri-mesterly newsletter entitled *Emerging Solutions in Pain*, a repository website by the same name *EmergingSolutionsinPain.com* and the sponsorship of the breakthrough pain category on *pain.com*, the most popular pain website on the internet. Additional CME initiatives included a CME insert in *Neurology Review*, a CME insert in *Pain Medicine News* and an opioid dosing monograph.

The local and regional CME Symposia represented the greatest effort in 2003 and allowed for the scientific exchange of extensive information on diagnosis and management of various pain states using a field driven system to control logistics. Sales representatives were allowed significant involvement in the logistical aspects of the regional and local CME programs. The initial goal for the sales force was for each PCS representative to assist in the scheduling of approximately four local programs for a total 316. The Medical Liaison Managers also had the ability to set up CME programs on a regional level for their respective territories, and were expected to do at least one program each for a total of 13. The total number of programs executed may fall shy of original expectations based on the pending sales force changes.

The tri-annual newsletter, *Emerging Solutions in Pain*, currently has a circulation of over 11,000 clinicians (8,000+ physicians and 2000+ nurses). The newsletter allows for communication of information on diagnosis and management of various pain types, including BTCP in two distinct media: written and CD-ROM. The accompanying website serves as a repository for all CME programs created.

### *Promotional Medical Education Programs*

Sales-driven Medical Education Programs (MEPs) are also a critical component of the educational efforts for ACTIQ. In 2003, over 800 sales-driven MEPs will be executed with greater than 1500 clinicians exposed to ACTIQ promotional messaging.

### *Advertising Campaign*

The concept currently in use for ACTIQ is the "bell" concept and was developed early in 2001. This concept has been utilized in all branded promotional and advertising materials since. Market research in 2002 showed that the concept was still successful, however, with some minor changes it would be even more effective. Keeping the "bell" concept has allowed for consistency in the branding of ACTIQ, while minor adjustments have made it even more effective. These minor adjustments included adding the headline

"When Onset Matters...ACTIQ On Call" and the tagline "When Onset Matters", although balance is required when making these statements. The most current journal advertisements can be viewed as Appendix 1.

In July 2003, a Campaign Tracking Study (CTS) was initiated with ACNielsenHCI to evaluate the concept's overall effectiveness. More specifically, the study will measure physicians' ability to recognize and recall the advertisement as well as the believability, relevance and uniqueness of specific messages within the advertisement. Similar feedback will also be gained utilizing a detail piece. Participating physicians will total 150, including 50 oncologists and 100 pain/anesthesiologists. Results will be available in Q4 2003 and will be used to modify the campaign if needed.

## I. MARKET DYNAMICS

### *Opioid Market*

The prescription opioid market can be divided into two major categories:

- Short-acting opioids
- Long-acting opioids

### *Short-Acting Opioids*

The short-acting opioid market can be further subdivided into two distinct categories:

- Short-acting pure opioids
- Combination product (e.g., opioid plus NSAID)

Currently, short-acting opioids (both pure opioids and combination products) are commonly used to treat opioid naive patients suffering from acute pain and recurrent or episodic pain, as well as opioid tolerant patients suffering from breakthrough pain. Acute pain is loosely defined as pain of relatively short duration elicited by injury of body tissue and activation of nociceptors (e.g., injury, surgery). Recurrent or episodic pain refers to intermittent occurrences of pain, with episodes lasting for a relatively short duration but occurring across an extended period of time (e.g., migraine headaches, sickle cell crisis); there is not a persistent-background pain component. Breakthrough pain is defined as a transitory flare of pain that occurs on a background of otherwise stable, persistent pain in patients receiving chronic opioid therapy.

Currently available short-acting opioids provide onset of analgesia over a range of 30-60 minutes while the duration of action ranges from 4-6 hours. As the name implies, these products have a "shorter" duration of effect than longer acting agents. The pervasive misperception among pain physicians is that the onset of analgesia that they provide is more rapid than oral long-acting opioids. This misperception is patently untrue. The onset of analgesia of short-acting agents (approximately 30-60 minutes) is practically identical to oral long-acting opioid products. A study published in the *Journal of Pain and Symptom Management* in October 1999 entitled "Can a Controlled-Release Oral Dose Form of Oxycodone Be Used as Readily as an Immediate-Release Form for the

"Purpose of Titrating to Stable Pain Control?" demonstrated that the median time to onset of pain relief was 45 minutes for 30mg of immediate-release oxycodone and 41 minutes for 30mg of controlled-release oxycodone. This data helps to prove that the currently available oral short-acting opioids do not offer any clear advantage over oral long-acting agents with respect to onset of analgesia. Furthermore, the term "immediate-release" is often considered a misnomer. Immediate-release refers to the fact that these products do not provide a controlled-release of medication over an extended period of time, as do the long-acting opioids. A chart of the short-acting pure opioids is included as Appendix 2.

#### *Long-Acting Opioids*

Long-acting opioids are most commonly prescribed to treat the persistent pain component of chronic pain in patients who are considered opioid tolerant. Chronic pain is loosely defined as pain that persists for a specified time that is arbitrarily determined (e.g., 3 months or 6 months), or beyond the expected period of healing. The duration of analgesia ranges from 8-72 hours, while onset of analgesia ranges from 45 minutes to 12 hours. The convenience afforded by the duration of analgesia is the key benefit of long-acting opioid products. The onset of analgesia is not a differentiating factor for long-acting opioids. A chart of the long-acting opioids is included as Appendix 2.

#### *Evolving Pain Guidelines*

Opioid use is currently classified by potency by the WHO (World Health Organization) Three-Step Analgesic Ladder. The WHO ladder system of pain management is segmented by the degree of pain: mild to moderate, moderate to severe, and severe. The ladder matches each level of pain to the potency of medications with more potent medications at each step. Adjuvant medications are also incorporated into the WHO ladder.

Most key opinion leaders view the WHO Three-Step Analgesic Ladder as somewhat outdated. For example, major flaws of the WHO ladder include the absence of the concept of BTP and the recommendation of combination product use for moderate to severe pain. The American Pain Society (APS), the WHO and other pain organizations will be publishing various pain treatment guidelines in 2003. Treatment guidelines for some chronic pain syndromes were completed and published in 2002 including, osteoarthritis (OA), rheumatoid arthritis (RA) and sickle cell anemia.

Overall, newly revised/developed guidelines should offer a vast improvement over the archaic WHO ladder and should be an important step in increasing awareness of the proper assessment and treatment of BTP and the use of opioids in pain states such as OA, RA and others. As these newer, more aggressive guidelines are adapted, BTP becomes more widely accepted as a clinical entity in need of treatment, and the characteristics of BTP are better understood, we will have the opportunity to position ACTIQ as the ideal treatment in the management of BTP.

## J. COMPETITION

### *Competitive Companies*

The major companies in the pain market place currently marketing pain medications (i.e., not devices) include Purdue Pharma, Janssen, Abbott Laboratories, Elan, Ligand, Endo and Cephalon, with Purdue Pharma and Janssen being the dominant market leaders. These companies have primarily focused on the outpatient chronic pain market for long-acting, sustained release products (although most offer both long and short-acting products), but many companies, such as Watson Pharmaceuticals and CIMA are in various stages of development with short-acting compounds which may be indicated for BTP or BTCP. A comprehensive list of potential competitors is listed as Appendix 3.

### *Long-Acting Opioids: Competitor or Not?*

The currently marketed long-acting products are not considered direct competitors of ACTIQ, however, in a certain sense they remain as a competitive barrier to additional ACTIQ use. In general, these products have indications for "moderate to severe" pain in opioid tolerant patients and are positioned for the treatment of all types of chronic pain, including both malignant and non-malignant. As mentioned previously, the duration of action for long-acting opioids ranges from 8-72 hours, while the onset of analgesia ranges from 45 minutes to 12 hours. All of the manufacturers of long-acting opioids, especially Purdue Pharma and Janssen, have been educating physicians over the last several years about the ability to reduce and/or eliminate the need for BTP medications by merely increasing the level of the persistent pain medication to cover episodes of BTP. In the rare instances that a patient experiences BTP (i.e., the long-acting medication is perceived to have "failed" at a specific moment), they espouse that a short-acting medication can be prescribed as a "rescue medication." Many of these long-acting, sustained release products have complementary short-acting products that have been traditionally promoted for acute and episodic pain. Although their use is indicated for moderate to severe pain only, many of these short-acting products are being promoted for use as "rescue medication" to be used along with the long-acting counterpart. As mentioned previously, the onset of analgesia of oral short-acting opioids ranges from 30-60 minutes. This delayed onset of analgesia may not provide relief rapidly enough to be effective to control a typical BTP or episodic pain episode.

Education regarding the independent assessment and treatment of both persistent pain and BTP will continue to be a major objective in 2004.

### *ACTIQ's Competitors: Direct and Indirect*

ACTIQ's direct competitors are the pure short-acting opioids. The branded formulations of these opioids are listed in Appendix 3. The use of other currently available oral short-acting pure opioids for the treatment of BTP is less than ideal due to a lack of rapidity of analgesic effect that they afford. ACTIQ's clear and distinct advantage over the currently available products in this category is its rapidity of onset of analgesia.

Opioid combination products, although prescribed for the treatment of BTP, are not truly direct competitors of ACTIQ for the following reasons:

- Limited dosing flexibility due to low opioid dosage options (for use in mild to moderate pain only)
- Dose ceiling effect due to presence of NSAID (intolerable side effects)
- Not being aggressively promoted for the treatment of BTP
- Use in BTP and episodic pain occurring as a result of physician ignorance.

As previously stated, long-acting opioids are not considered a direct competitor in the BTP market; however, they may be viewed as an indirect competitor for ACTIQ. Various manufacturers have aggressively educated physicians that when appropriately medicated with a long-acting opioid, patients should not experience BTP, or should experience it minimally. Although not congruent with the opinions of most key opinion leaders, many community-based physicians currently adhere to this philosophy, thus turning the long-acting opioids into "pseudo competitors." Re-educating physicians will be a challenge.

#### Pure Short-Acting Prescription and Market Share Analysis

Short Acting Opioid Class	TRx MAT 06/02	MAT 06/02 %	TRx MAT 06/03	MAT 06/03 %	?
Oxycodone HCL (G)	992,798	22%	1,690,832	31%	70%
Morphine Sulf (G)	924,062	21%	1,241,729	23%	34%
Hydromorphone HCL (G)	482,124	11%	675,206	12%	40%
Roxicodone (B)	681,308	15%	576,044	11%	-15%
ACTIQ (B)	124,915	3%	247,256	5%	98%
Roxanol (4 types) (B)	382,674	9%	236,472	4%	-38%
Dilaudid (3 types) (B)	237,653	5%	212,428	4%	-11%
OXYIR (B)	302,097	7%	225,909	4%	-25%
MSIR (B)	180,924	4%	161,733	3%	-11%
Codeine (G)	98,730	2%	102,632	2%	4%
OXYFAST (B)	90,226	2%	58,853	1%	-35%
<b>Class Total</b>	<b>4,497,511</b>	<b>100%</b>	<b>5,429,094</b>	<b>100%</b>	<b>21%</b>

(G) = Generic

(B) = Branded

For MAT June 2002 versus MAT June 2003, the total pure short-acting opioid TRx market grew 21%. All of the generic products showed growth while all of the branded products except ACTIQ had negative growth. ACTIQ prescriptions have grown 98%, a faster rate than any other pure short-acting product, branded or generic. For this same time period ACTIQ increased its market share from 3% to 5%, while all the other branded products lost market share.

### **III. COMMERCIAL INFRASTRUCTURE UPDATE**

#### **A. SALES AND MARKETING**

While the size of the commercial infrastructure that supports ACTIQ remained fairly modest in 2003, Cephalon marketing and sales continued to excel and drive the product forward.

The PCS sales force expanded from 60 representatives in 2002 to 79 representatives in 2003. The addition of 19 PCS sales representatives created slightly smaller, more manageable sales territories and may have contributed to the continued success of ACTIQ. Additionally, a second Product Manager was added to the ACTIQ marketing team. This addition allowed for the implementation and execution of a greater number of marketing initiatives, as well as optimizing financial resources placed behind the brand.

Further expansion of both the sales force and ACTIQ marketing team will be required to move ACTIQ to the next level of productivity. Assuming that the Cephalon PCS and CNS sales forces will be combined and possibly expanded, this will certainly extend the reach of the brand. However, this action may not provide for the focus or frequency necessary to truly impact the brand's share of voice among key targets, which could detrimentally affect Cephalon's ability to meet 2004 ACTIQ TRx and sales targets. To meet TRx and sales targets, it will be imperative to accomplish the following three critical success factors:

- **Sales Force Training**
  - Providing product knowledge and pain market dynamic sales training to all new representatives will be critical to any expanded selling efforts
- **Sales Force Focus and Commitment to Selling ACTIQ (especially sales management support)**
  - Obtaining sales force focus and commitment to selling ACTIQ can only be accomplished through 1) marketing providing this motivation through passion for the product, quality promotional selling tools and complementary medical education tools and 2) sales providing appropriate sales bonus incentive and direction for execution in the field
  - Territory management and spending appropriate selling time on each of Cephalon's products
- **Accurate and Appropriate Targeting**
  - Marketing must provide excellent sales targets to allow for proper targeting and maximal presence with the most appropriate ACTIQ targets
  - Sales management must provide excellent direction and coaching regarding targeting to ensure appropriate selling time for each product

## IV. SWOT ANALYSIS AND KEY MARKETING ISSUES

### A. ACTIQ SWOT ANALYSIS

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> <li>• Rapid onset of analgesia</li> <li>• OTS delivery and onset of action provides patients with portability, convenience, and control</li> <li>• Well known opioid with proven efficacy and safety profile – fentanyl</li> <li>• Solid clinical database within cancer patient population</li> <li>• Large base of published product literature within cancer</li> <li>• Anecdotal positive impact on Quality of Life</li> <li>• Core product characteristics appropriate for treatment of BTP</li> </ul>	<ul style="list-style-type: none"> <li>• Narrow indication</li> <li>• Limited promotional flexibility due to Subpart H approval (Risk Management Plan and 30-day mandatory FDA review)</li> <li>• Lack of data and publications supporting utilization, QoL and simplified titration</li> <li>• Cannot make the claim "rapid onset" despite being the most rapid acting "oral" agent and trials proving onset in 15 minutes</li> <li>• High acquisition cost – value proposition not well understood</li> <li>• Perceived cumbersome titration process</li> <li>• No equianalgesic dosing guidelines</li> <li>• Perceived safety concerns</li> </ul>
OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> <li>• Physician eagerness to evaluate drug outside of BTCP – creates opportunities to generate data in needed areas</li> <li>• Increased focus on pain management from JCAHO (5<sup>th</sup> vital sign)</li> <li>• Opioid use being recommended and incorporated into a variety of pain treatment guidelines</li> <li>• Expansion of sales force to increase promotional reach</li> </ul>	<ul style="list-style-type: none"> <li>• Diminished selling efforts due to lack of product focus with expanded sales force selling all three Cephalon products</li> <li>• Negative patient and/or prescriber reaction to new (compressed powder) formulation of ACTIQ</li> <li>• Increased scrutiny by DDMAC of all promotional materials submissions for mandatory 30-day review</li> <li>• Continued Subpart H classification and RMP restrictions/obligations</li> <li>• Increased counter-detailing from competitors as ACTIQ gains market share</li> <li>• "Opiophobia" within pain market due to recent publicity around abuse issues</li> <li>• Competitors continuing to be prescribed for BTP without having done any trials or having a label/indication for BTP</li> <li>• Increased reimbursement difficulties</li> <li>• Minimal support with phase IV and publications</li> <li>• Dental caries issue becomes larger</li> <li>• Potential future branded competitors: BTrans (Janssen), Oravescient (Cima), etc.</li> </ul>

## B. KEY MARKETING ISSUES

Seven key marketing issues must be addressed in 2004. The first four of these key issues have persisted since ACTIQ was launched in 1999.

- **Low awareness in the assessment and treatment of BTP**

Many of our targeted physicians and healthcare providers believe that they are managing chronic pain adequately despite the fact that most pain assessment tools do not include questions or pain scales specific to BTP. BTP must become recognized as a critical component of chronic pain that must be assessed and treated as a distinct and separate entity from persistent pain.

- **Low product awareness among patients and prescribers**

Many physicians and healthcare providers remain uninformed about ACTIQ and its benefits in treating BTP. Increasing the awareness of ACTIQ and its key differentiating benefits of rapid onset of analgesia, portability, convenience and control will be critical to continuing the tremendous growth seen with ACTIQ in 2003.

- **Limited number of key opinion leaders (KOLs)/advocates**

Both marketing and public relations must develop/renew relationships with KOLs in the field of pain management in order for ACTIQ to gain the exposure and support needed to become a first line treatment option for BTP. Key opinion leaders must be made aware of the key messages and benefits of ACTIQ and be encouraged to incorporate ACTIQ as part of pain treatment guidelines. At this time, there are no guidelines specific to BTP and BTP is ignored or rarely mentioned in most pain treatment guidelines.

- **Limited clinical data and publications**

Developing data and/or publications in the following areas will continue to be crucial in growing the use of ACTIQ, as well as overcoming current and future reimbursement hurdles.

- Efficacy/safety/utilization data in appropriate therapeutic areas requiring rapid analgesia in opioid tolerant patients
- Simplified titration information
- Quality of life data

Decisions to be made in the near future regarding ACTIQ and future potential pain products will affect the course of developing this data, which could be generated from open label trials/phase IV research or retrospective studies/publication efforts.

- **Potential branded competitors in 2005**

It is expected that other products with similar benefits will become available as early as 2005 and may claim to have an even faster onset than ACTIQ. Cephalon must anticipate and prepare for the launch of these products and proactively deliver the right messages regarding the onset and safety of ACTIQ to key targeted market segments.

- **Physician fear/concern of prescribing opioids ("Opiophobia")**

Opioids have only become more widely prescribed for pain in the outpatient setting over the last 10 to 15 years. Even today there are still concerns among clinicians such as abuse, addiction, accidental ingestion and diversion, especially as a result of the

Oxycontin abuse issue which surfaced in 2001. Additionally, physicians are being scrutinized by both their peers and government agencies with respect to their practice of pain medicine and in particular their opioid prescribing habits. It is critical in today's world of pain medicine that physicians understand how, when and where to prescribe opioids safely. These concerns may have specifically resulted in physicians shying away from prescribing ACTIQ in the past as many physicians relate rapid analgesia with rapid onset of euphoria and thus the potential for abuse. As an emerging competitor in the world of pain medicine and to ensure ACTIQ's continued acceptance as the ideal BTP treatment, Cephalon must attempt to set itself apart from other companies marketing opioids and assist physicians by providing a mechanism to appropriately and safely prescribe opioids.

Two additional key issues the ACTIQ marketing team must be concerned with in 2004 include the following.

- **Combining of sales forces: potential loss of focus on ACTIQ**

With 79 pain care specialists, the direct promotional reach for ACTIQ in 2003 is somewhat limited, especially in contrast to the sales forces of other pain market leaders. However, despite this limited reach, the PCS sales force has had only ACTIQ to sell, which has provided for tremendous focus in their selling efforts. Also, because selling ACTIQ is challenging and time intensive due to its restrictive label and a lack of clinical data, the direction from marketing since the April 2001 Cephalon re-launch has been to focus on a core group of high potential targets with the right frequency (i.e. hold their hands until they were comfortable with prescribing). This strategy has proven highly effective as ACTIQ has grown tremendously since being re-launched by Cephalon and was modified only slightly last year by directing the sales force to expand their core of targets. This new strategy also proved productive as ACTIQ sales are projected to eclipse budget by 6% in 2003. Also, for MAT June 2003, there are still only 300 prescribers who account for 50% of all ACTIQ prescriptions and only 1302 that account for 80%. Combining and possibly expanding the PCS and CNS sales forces in 2004 creates both opportunities and challenges for ACTIQ. ACTIQ marketing must be prepared to maximize the opportunities and mitigate potential downfalls.

- **Potential negative reaction to new compressed powder formulation**

Thus far in 2003, the transition to the new formulation of ACTIQ has provided numerous negative responses from both patients and clinicians. It will be critical to our immediate and future success to understand the impact and scope of these negative responses and plan to potentially address or mitigate them in the second half of 2003 and in 2004.

## V. PRODUCT VISION AND POSITIONING

### A. ACTIQ VISION

*Short-Term Vision:* ACTIQ is a unique, revolutionary and highly beneficial option to treat patients with BTP.

*Long-Term Vision:* ACTIQ is the ideal first-line option to treat BTP.

Although ACTIQ prescriptions continued to grow at an impressive rate in 2003, ACTIQ must still be established as a valid first-line treatment option for BTP. Additionally, we must continue to strive to educate the pain community about the importance of assessing and treating BTP independently from persistent pain. In order to accomplish the long-term vision for ACTIQ, the following needs must be met.

- Development of clinical data and/or publications discussing:
  - Efficacy/safety/utilization data in appropriate therapeutic areas requiring rapid analgesia in opioid tolerant patients
  - Simplified titration information
  - Quality of life data

Due to minimal/ineffective internal support and focus on publication projects with high commercial value, marketing undertook responsibility for driving publication efforts in 2003. Marketing will continue to drive the strategic and tactical execution of these efforts in 2004 or until such time that adequate and appropriate internal support is provided.

- Expanded and highly effective promotional and medical education efforts
- Develop a tool(s) to support reimbursement issues
- Expand direct promotional reach without sacrificing focus or frequency
- Increase ACTIQ marketing personnel and financial resources

## B. ACTIQ 2004 POSITIONING

ACTIQ's positioning will continue to focus on its key differentiating feature and benefit.

- **Key Feature:** ACTIQ utilizes a unique oral transmucosal delivery system (OTS™) for rapid absorption of fentanyl
- **Primary Patient Benefit:** ACTIQ's oral transmucosal delivery system provides the most rapid onset of action among all non-invasive, shorter acting opioids.

### *ACTIQ 2004 Positioning Statement:*

The 2004 positioning statement for ACTIQ reflects the above key differentiating feature and benefit and, as it should at this point in its lifecycle (no changes in label/indication or in the competitive set), is identical to the 2003 positioning statement. The 2003 positioning statement for ACTIQ was created to be simple, direct and allow for broad therapeutic application as deemed appropriate by the prescriber.

**ACTIQ is fentanyl in a unique oral transmucosal delivery system that provides the most rapid onset of analgesia of any non-invasive opioid formulation available.**

### *Patient Profile*

At a consultant meeting in 2003, a discussion took place regarding the future development of ACTIQ and other pain products. As the group of physician consultants debated the patient populations most in need of a product that offers the primary patient benefit of ACTIQ, one physician posed the question, "What pain patient doesn't want or need rapid pain relief?" Based on countless interactions with physicians at consultant meetings, advisory panels and in market research, this statement accurately reflects the feeling of most pain patients regarding their desire for obtaining rapid analgesia once pain begins. Therefore, the ideal patients for ACTIQ are those that will benefit from ACTIQ's rapid onset of analgesia as well as its portability, convenience and control.

Again, based on the feedback we have received from our consultant meetings, market research and continued growth of the product in 2003, it is apparent that the physician who posed the question above was correct. ACTIQ's primary patient benefit of rapid analgesia and solid safety track record as a BTP medication since its April 1999 launch have made it a medication of choice for many prescribers looking to provide rapid analgesia for their patients.

## VI. MARKETING AND PROMOTIONAL STRATEGY

### A. MARKETING GOALS AND OBJECTIVES

#### *Marketing Goals*

The 2004 ACTIQ marketing plan will seek to address the issues previously listed and achieve the following goals:

- Increase awareness of ACTIQ and BTP among targeted physician specialties/segments and patient populations
- Increase the overall number of ACTIQ prescribers
- Increase the number of prescribers in the top five TRx and Units prescribing deciles (i.e. move prescribers along the product adoption curve from dabblers to users/adopters)
- Increase ACTIQ prescriber productivity and prescriber retention
- Continue to develop relationships with KOLs in pain management
- Develop a tool(s) to assist with managed care/Medicaid reimbursement
- Continue to build on clinical data/publications initiated in 2003 to meet prescriber and advisor recommendations regarding:
  - Utilization data in various pain types/therapeutic applications
  - Simplified titration/dosing
  - Quality of life (improved patient functioning)

#### *Marketing Objectives*

Factory sales and prescription volume objectives for 2004 are as follows.

2004	Gross Sales	TRx
Q1	\$ 73,871,509	19,300
Q2	\$ 82,383,393	20,453
Q3	\$ 92,872,820	17,316
Q4	\$ 105,332,181	23,101
<b>2004 TOTAL</b>	<b>\$ 354,459,903</b>	<b>435,419</b>

### B. MARKETING STRATEGY

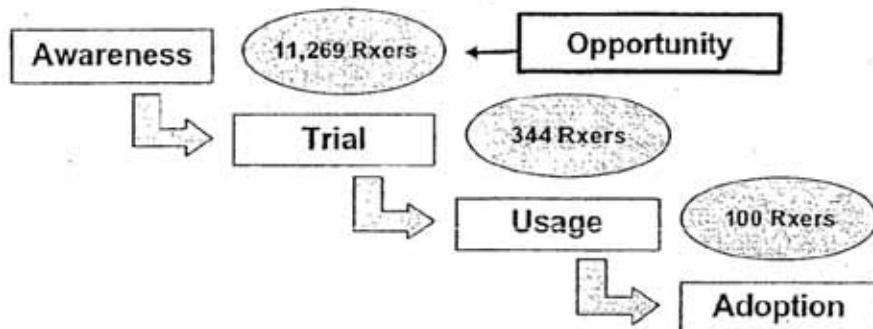
#### *Overall Promotional Strategy*

As stated above one of the key objectives for 2004 will be to drive physicians along the product adoption curve from awareness and trial to usage and adoption. Therefore, the overall marketing strategy for 2004 will continue to build on the successful platform developed in previous years, which will be to 1) raise awareness of BTP and ACTIQ through PR and marketing driven awareness initiatives and 2) differentiate ACTIQ from its competitors by educating clinicians about the core product benefits (rapid onset of

analgesia, portability, convenience and patient controlled administration) through targeted medical education initiatives.

When looking at the product adoption curve, 11,269 of the 11,713 total ACTIQ prescribers fall into the "trial" range. These 11,269 prescribers comprise ACTIQ TRx prescribing deciles 0-4 and represent a tremendous opportunity to grow ACTIQ prescriptions. Only 444 prescribers fall within the "usage" and "adoption" range of the adoption curve. The 344 "users" comprise the ACTIQ TRx prescribing deciles 5-7 and the 100 "adopters" comprise deciles 8-10. The overall promotional strategy for 2003 will be to move prescribers from awareness and trial to usage and from usage to adoption.

### 11,713 Total ACTIQ Prescribers (MAT 4/03)



#### *Promotional Strategy by Key Marketing Issue*

**Issue:** Low awareness in the assessment and treatment BTP

**Strategy:** Educate key targeted physician specialties and patient populations about the importance of assessing BTP and the benefits of treating it with ACTIQ

Through promotional, educational and public relations efforts, marketing will strive to increase awareness of BTP amongst targeted physician specialties and patient types. Based on proven success, peer-to-peer promotional efforts and CME will be the primary means used to educate physicians, pharmacists and nurses. PR efforts will be the primary method of reaching and educating patients. In addition, an enhanced convention presence including a larger, ACTIQ-dedicated booth and an enhanced media presence will be employed in 2004.

**Issue: Low product awareness among patients and prescribers**

**Strategy: Strengthen the association of ACTIQ and its key patient benefits through improved awareness and medical education**

Market research was conducted in 2002 to obtain feedback from physicians to determine which key messages best conveyed ACTIQ's key differentiating benefits. These key messages, along with the current brand concept (i.e., the bell concept) developed in 2001 and enhanced in 2002 and 2003, will continue to play a critical role in raising awareness of ACTIQ. Marketing will implement high reach promotional and educational efforts to contact as many potential ACTIQ prescribers as possible. Additionally, more specific targeted promotional and educational efforts will be implemented to raise awareness among the highest potential prescribers. In order to maintain the tremendous growth seen in 2003, awareness of ACTIQ associated with its primary patient benefit of rapid analgesia must be enhanced.

**Issue: Limited number of KOLs/advocates**

**Strategy: Build/renew relationships with KOLs in pain management and targeted physician specialties through consultant meetings, advisory boards and PR efforts**

Great strides were made in renewing and developing relationships with KOLs in 2003, yet this remains a key marketing issue for ACTIQ. Again, marketing and product communications will initiate/renew contact with KOLs with the objectives of: 1) receiving guidance in the development of educational initiatives, clinical trials and publication efforts, and 2) empower advocates to incorporate BTP and ACTIQ into pain treatment guidelines and educational initiatives. At this time there are no treatment guidelines specific to BTP and very few mentions of BTP are found among the various pain treatment guidelines.

**Issue: Limited clinical data and publications**

**Strategy: Drive the direction of phase IV research and publication efforts to be consistent with commercial needs**

ACTIQ's narrow indication and accompanying risk management program (RMP) are its most significant promotional limiting factors. Additionally, a lack of data regarding ease of dosing/titration and quality of life also hinder physician acceptance of ACTIQ. Three distinct publication efforts were initiated in 2003 focused to address/highlight these three areas: 1) ACTIQ utilization, 2) simplified dosing and titration, and 3) ACTIQ's impact on QoL. Also, a clinical trial aimed at defining the prevalence and characteristics of BTP among non-malignant pain patients is planned to begin in 2003, but may not commence due to budget constraints. This study, and hopefully others to follow, should demonstrate the need for a product with ACTIQ's clinical profile in non-malignant BTP. Due to its primary patient benefit and the understanding of fentanyl among pain physicians, there is substantial opportunity for ACTIQ's continued acceptance as the ideal treatment option for BTP. In order to continue the tremendous growth observed in the last several years, it will be imperative that Cephalon continue to provide data related to these areas and others to current and potential prescribers.

**Issue: Potential branded competitors in 2005**

**Strategy: Proactively position ACTIQ to defend its market share against future branded competition**

Competitive intelligence was implemented in 2003 and found that ACTIQ may face branded competition as early as late 2005. Marketing must continue to keep a close watch and determine the best strategy for defending ACTIQ's position in the pain market. It will be imperative for the ACTIQ marketing team to remain flexible regarding a change in ACTIQ's key messaging and positioning as we become aware of new competition and how they plan to position themselves in the market. Marketing must be careful not to negatively position a branded competitor with faster onset of analgesia than ACTIQ, especially if Cephalon plans to launch a product in the future with a more rapid onset. Key messages for ACTIQ may need to focus on the safety aspects of the product (i.e., the handle, RMP and safety track record). Close coordination with the ACTIQ business strategy team must be maintained to determine the best approach. Once a strategy is determined in 2004, marketing and sales will proactively educate healthcare providers of the advantages ACTIQ has over any future potential competitors.

**Issue: Physician fear/concern of prescribing opioids ("Opiophobia")**

**Strategy: Provide a mechanism to facilitate physician needs for appropriate and safe opioid prescribing habits**

Many clinicians who medically manage pain with opioids have concerns such as abuse, addiction, accidental ingestion and diversion. Additionally, scrutiny of opioid prescribing practices by government agencies exacerbate this fear and may affect the opioid prescribing habits of some physicians. As stated previously, these concerns may have specifically resulted in physicians avoiding prescribing ACTIQ, especially since many physicians relate rapid analgesia with rapid onset of euphoria and thus the potential for abuse. Based on the feedback from consultants meetings and advisory panels, it has been determined that Cephalon must attempt to assist physicians by providing a mechanism to prescribe opioids appropriately and safely. ACTIQ marketing has determined that a non-branded promotional effort/program called *Reduce the Risk* will be implemented in 2004 with this specific goal in mind. The objectives of the program will be as follows

- Create local communities of healthcare providers involved in the world of pain management
- Optimize patient care
- Reduce the risk of prescribing opioids by encouraging medically appropriate measures such as, but not limited to, accurate documentation, appropriate patient referral to other specialists, patient drug screens, etc.

Additionally, the ACTIQ marketing team is working with a physician advisor and an independent 3<sup>rd</sup> party to develop a screening tool to be used to highlight potential abuse issues with patients. Each of these initiatives, the *Reduce the Risk* program and the screening tool, will be tremendous, value-added tools for the sales force and help to set Cephalon apart from its competitors.

**Issue: Combining of sales forces: potential loss of focus on ACTIQ**

**Strategy: Motivate and focus selling efforts on ACTIQ by providing quality selling tools, solid sales targets and passion for the product**

As the PCS and CNS sales forces are combined and possibly expanded to extend our promotional reach, the fact that all three Cephalon products will be sold by the sales force may limit the sales force's ability to focus promotional efforts with the right frequency to our most productive targets. It will be crucial in 2004 for the ACTIQ marketing team to 1) provide passion for selling ACTIQ based on patient benefit, 2) motivate the sales force to focus selling efforts with the right frequency of calls, 3) provide the sales force with quality selling tools and 4) provide the sales force with the best potential prescribing targets to help them manage their territories as efficiently as possible. Hopefully, these activities will allow for ACTIQ to be successful and meet TRx and sales targets while Cephalon implements a large, combined sales force comprised of persons with little or no previous selling experience in the pain market.

**Issue: Potential negative reaction to new compressed powder formulation**

**Strategy: Fully assess and evaluate any lingering negative reaction and develop a plan of action to address/correct it**

It will be critical to fully understand the impact and scope of any/all negative responses to the new formulation of ACTIQ and plan to potentially address or mitigate them during the remainder of 2003 and in 2004 if they persist. Due to the fact that the transition is still underway and the full scope of the issue has not yet been determined, it is not possible to set a strategy to address this potential issue at this time. It will also be important for Cephalon to fully understand and consider the scope and severity of any negative reaction to the new formulation when planning to potentially develop and transition to a sugar free formulation in the future.

## VII. TACTICAL PLAN

### A. ACTIQ KEY MESSAGES

Message and positioning testing was done in April 2002 to determine the key messages that most effectively convey ACTIQ's key differentiating benefits and appropriately position the product. ACTIQ will continue to be positioned in 2004 as fentanyl in a unique oral transmucosal delivery system that provides the most rapid onset of analgesia of any non-invasive opioid formulation available through the communication of the following key product messages, which tested highest amongst physicians in April 2002:

- *Efficacy:* The main benefit of ACTIQ is its time to onset of analgesia.
- *Safety:* In clinical trials, the safety and efficacy of ACTIQ were established in opioid tolerant cancer patients receiving both long-acting oral and transdermal opioids.
- *Side Effects:* The adverse events seen with ACTIQ are typical opioid side effects. Frequently, these adverse events will cease or decrease in intensity with continued use of ACTIQ, as the patient is titrated to the proper dose.
- *Dosing and Titration:* ACTIQ should be taken along with the patients' longer-acting cancer pain medication.
- *Convenience/Ease of Use:* ACTIQ's oral transmucosal delivery system and onset of action provides patients with portability, convenience and controlled administration.
- *Delivery System:* ACTIQ utilizes a unique oral transmucosal system (OTS™) for rapid absorption of fentanyl.
- *MOA of Fentanyl:* High lipophilicity of oral transmucosal fentanyl allows for rapid absorption across the oral mucosa into the blood and distribution into the CNS – a process with a 3-5 minute half-life.

Most of these key messages appear in some fashion in promotional materials, including the most recent journal advertisement (Appendix 1), sales aids and booth panels. In the journal advertisement and booth panels, these key messages, along with the headline "When Onset Matters...ACTIQ on Call" and the tagline "When Onset Matters" help to drive home the core patient benefits of ACTIQ.

### B. TARGET AUDIENCE

The ACTIQ target audience includes oncologists, pain specialists and physicians skilled in the use of opioids. The targeting methodology used in 2003 will be repeated to establish targets for 2004.

## C. CORE TACTICAL PLAN

### *Overall Tactical Approach*

The majority of marketing resources will be allocated to tactics that are considered 1) most effective in delivering ACTIQ's key messages to our target audiences and 2) most effective in educating and raising awareness of ACTIQ and the clinical entity of BTP. Based on historical successes, the tactics most effective in accomplishing the aforementioned criteria include peer-to-peer educational programs such as CME initiatives and sales-driven medical education programs (MEPs). As in 2003, consultant meetings and physician and nursing advisory boards will be implemented to help identify the most appropriate and effective tactical programs and formats, to assist in the development of clinical research and publications plans, and to develop programs to raise awareness of BTP/ACTIQ among both patients and clinicians. Lastly, due to insufficient internal support, marketing will again drive key publication efforts in 2004. Therefore, the 2004 ACTIQ tactical initiatives can be broken down into three broad categories:

- Promotional Tactics
- Medical Education Initiatives
- Advisory Tactics

The following is a brief overview and description of the 2004 ACTIQ tactical plan. The 2004 Tactical Plan By Key Marketing Strategy, 2004 Tactical Implementation Timeline and 2004 Tactical Budget are attached as Appendices 4, 5 and 6 respectively.

### *Promotional Tactics*

#### **• Direct Selling Support Pieces**

Marketing will provide the sales force with appropriate and effective sales support materials. These materials will be updated to reflect the new formulation in the second half of 2003. All support pieces will contain ACTIQ key messages as listed previously, as well as the brand colors and current brand concept. Sales representatives will continue to receive a sufficient amount of coupons as they have proven incredibly effective in generating new patient starts.

2004 promotional sales materials will include:

- Core Sales Aid
- ACTIQ Coupons
- Pocket Dosing Guides
- Physician FAQ
- Patient FAQ
- Reimbursement Guide
- Patient Use Q&A Tear pads
- BTP Wall Charts and Counter Cards
- ACTIQ Monograph
- Promotionally Approved and WLF Reprints

- **Direct Mail**

Direct mailing efforts for 2004 will focus on accomplishing the following key objectives:

- Complement direct selling efforts
- Raise awareness of BTP and ACTIQ among key targets
- Deliver ACTIQ key messages to specific market segments
- Maintain/continue communication with previous direct mail responders

Most direct mail targets will be both marketing and sales targets. Therefore, the sales force will be provided with copies of each direct mail effort to familiarize themselves with what has been communicated to their physician targets.

- **Medical Meeting Presence**

Marketing plans to attend a minimum of nine national level conventions in 2004 and will focus on increasing and improving our presence at these meetings. The primary objectives will be to raise awareness and to brand both ACTIQ and Cephalon within the pain community. This will be accomplished through the utilization of a larger booth presence, CME symposia, consultant meetings and other medical meeting-specific promotional and educational efforts. Multiple new booth panels and a video focusing on the mechanism of action, OTS™ delivery, BTP characteristics and titration messaging will help to deliver key marketing messages, raise awareness of ACTIQ and differentiate ACTIQ from its competitors. A separate and distinct Medical Affairs area within the larger booth allows for questions regarding use of ACTIQ. It is crucial that ACTIQ/Cephalon maintain and/or increase its presence at these key meetings in order to be seen as a major player in the pain market. The 2004 Medical Meeting Schedule is attached as Appendix 7.

- **Internet Activity**

As in 2003, marketing will utilize *ACTIQ.com* to provide product specific information as well as BTP information to both physicians and patients. The site will be updated with compressed powder formulation information and visuals in Q3 2003.

- **Journal Advertisements**

Marketing will implement both a branded single page and a two-page spread in 2004 as in 2003. The current brand concept will remain the same and provide consistent branding for ACTIQ in 2004. Additionally, marketing will develop a non-branded BTP awareness advertisement with the ACTIQ branding elements to complement the branded advertisements that will appear in the same journals. Marketing plans to increase journal placements and ACTIQ's share of voice in the pain market. Additional market research will be performed in late 2004 to determine if any improvements can be made to the current concept and journal advertisements. The complete ACTIQ media plan is detailed in Appendix 8.

**2004 Journal Advertising Distribution**

<b>Pain</b>	Journal of Pain Journal of Pain & Symptom Management Pain Medicine Pain Medicine News Practical Pain Management
<b>Anesthesiology</b>	Anesthesiology Anesthesiology News
<b>Oncology</b>	American Journal of Oncology Review Journal of Clinical Oncology Journal of American Medical Assoc. – Cancer Demo Journal of Supportive Oncology Oncology Oncology Net Guide Oncology News International

***Medical Education Initiatives***• **CME programs**

As demonstrated in the past, continuing education programs are extremely effective in allowing for full scientific discussion of ACTIQ in the context of pure, balanced educational programs. Marketing plans to implement numerous CME initiatives in 2004 in a range of formats and venues. Current and on-going initiatives will be expanded and improved while a variety of new initiatives will also be employed. Substantial resources will be applied to CME programs this year due to the need to raise awareness and educate clinicians about BTP. CME programs for 2003 include:

- *Emerging Solutions in Pain* Tri-Annual Newsletter
- Local/regional CME symposia (*CEP Lecture Series*)
- Medical Meeting CME Symposia
  - Targeting APS, AAPM&R and ONS
- CME Teleconferences
- Direct Mail CME Monographs
- Direct Mail CME CD-ROMs
- Publication Inserts
- On-line CME offerings at WebMD/Medscape
- *Pain.com/breakthrough*
- *EmergingSolutionsinPain.com*
  - The website will be completely redesigned and relaunched in Q2 2004

- **Promotional Medical Education Programs (MEPs)**

Peer-to-peer selling is a highly effective means of developing ACTIQ prescribers and advocates. Sales-driven promotional MEPs have proven to be an effective way to convert ACTIQ dabblers into ACTIQ champions. In addition to the branded promotional MEPs available to the sales force, a non-branded promotional MEP initiative entitled *Reduce the Risk* will be developed and employed in 2004. The impetus for this program was a direct result from feedback received at consultant meetings from pain physicians regarding concerns about opioid abuse and addiction as well as concerns about prescribing opioids safely in today's legal environment. This program is an important undertaking for Cephalon despite the excellent safety record for ACTIQ. The goal of the program will be to build local communities of clinicians involved in the world of pain medicine, including pain specialists, oncologists, psychiatrists, addictionologists, pharmacists and nurses with the objectives of 1) optimizing patient care and 2) ensuring opioids are being prescribed appropriately and safely. Marketing will provide sufficient resources to the sales force to drive the implementation of sales-driven MEPs in 2004.

- **Publications**

Due to a lack of internal support, direction and expertise, the ACTIQ marketing team assumed responsibility for driving ACTIQ publications that would be of scientific interest and thus provide commercial value in 2004. The following areas were highlighted as areas in which publication efforts were needed:

- Simplified dosing/titration
- ACTIQ utilization
- ACTIQ impact on quality of life impact

Manuscripts focusing on each of these three areas will be submitted for publication in Q3 2003. Actual publication dates for these manuscripts will most likely be sometime in 2004 and will provide critical information that will educate physicians about BTP and the benefits of ACTIQ.

Additional publication efforts that can provide immediate commercial value will be identified at consultant meetings and advisory panels to be held in Q3 and Q4 2003 and a 2004 publication plan will follow.

#### *Advisory Tactics*

- **Consultant Meetings**

Marketing proposes to host approximately six consultants meetings in 2004 to better understand the educational and clinical needs of pain specialists at all levels of sophistication. These meetings will be held in a variety of locations throughout the country to better understand differences based on geography/region.

- **Consensus Meetings**

Marketing proposes to host approximately 12 consensus meetings in 2004. These meetings will be a cross sampling of disciplines brought together from various regions of the country in an attempt to come to consensus on specific scientific issues.

- **Advisory Boards**

Marketing will implement four separate advisory board initiatives in 2004.

- Marketing Advisory Panels
  - Comprised of thought leading physicians treating pain who can provide insight into educational needs and publication and research strategies.
- On-Line Advisory Panels
  - Comprised of ACTIQ prescribers (not KOLs) who can provide insight to guide educational programs and marketing initiatives.
- Abuse/Addiction Advisory Panel
  - Comprised of thought leaders in the areas of abuse and addiction who provide insight into education needs specific to this area.
- Nurses Advisory Panel
  - Comprised of both thought leading nurses as well as non-thought leading nurses who can provide insight into the educational and clinical needs of nurses.

#### D. ACTIQ 2004 MARKET RESEARCH PLAN

##### *Yearly Projects*

- **Market Dynamics Study**
  - Understand how the current drivers and perceptions of ACTIQ and competitors have changed over the past year
  - Understand how customers are utilizing ACTIQ
  - Awareness and usage measures
- **Patient Chart Study**
  - Understand ACTIQ use by strength, disease state, and therapy strategy
- **ACNielsenHCI**
  - Measurement of ACTIQ journal concepts
- **Patient Flow Analysis**
  - Capture patient utilization of ACTIQ compared to competitors

##### *Strategic Market Research Projects*

- **New User Analysis**
  - Understand how new users and targets perceive the message and the experience of using ACTIQ

- **Patient Research**
  - Understand patients' experiences with BTP and beliefs and experiences using ACTIQ
- **Patient Segmentation**
  - Understand the mix of ACTIQ prescribers and potential patients
- **Positioning / Messaging**
  - Revisit current positioning/messaging
- **Customer Gap Analysis**
  - Understand differences in ACTIQ experience and BTP that exist between physicians and patients

*Lifecycle Management*

- Complete any DD5 work (profile assessment)
- Exploration of DD6 (needs analysis for long acting opioid)
- Generic Defense
  - Understand if we can use pharmacists as a lever against generic substitution

#### E. PUBLIC RELATIONS PLAN

In 2003, much progress has been made in turning key relationships, including the Nurses Advisory Board, into tangible outcomes. Cephalon's visibility in the pain community continues to grow, and third party patient and professional groups are increasing their own focus on BTP.

The 2004 plan will build on these successes and broaden outreach to multiple audiences: consumers and caregivers/patient advocacy groups; media; thought leaders; professional organizations; nurses and allied healthcare professionals; and physicians. The plan takes into consideration how these audiences overlap and influence each other.

These strategies below serve as the basis for tactics that will enhance Cephalon's image as a partner in pain management; increase BTP and ACTIQ awareness in the pain and oncology communities; spotlight BTP as a distinct pain syndrome; and highlight ACTIQ as the only approved treatment for BTP.

- Position Cephalon as a player in the pain community
- Rally support from key leaders
- Open doors to new relationships
- Negotiate collaborations

- Communicate key BTP messages
- Associate BTP with ACTIQ brand
- Listen to clinicians' and patients' needs
- Link clinical knowledge to practice patterns

The core tactical initiatives for the 2004 ACTIQ PR plan are designed to improve awareness of and develop educational materials about BTP and treatment options; build consensus about BTP in the pain and oncology communities; strengthen relationships with third parties and key opinion leaders; and enhance media relations. The PR tactics can be broken down into four broad categories:

- Awareness and Education Initiatives
- Consensus Building
- Relationships with Third Party and Key Opinion Leaders
- Media Relations

#### *Awareness and Education Initiatives*

- **APF BTP Tools**

Support increased visibility and use of BTP educational tools – the Clinician Pocket Card and the Patient Pain Tracker – developed by the American Pain Foundation (APF). Drive messages to patients and caregivers through radio and print media campaigns, web chats, etc. Expand distribution of tools to clinicians and consumers.

- **Oncology Practice Survey**

Provide grant to third party to evaluate practices of oncologists to demonstrate anticipated gap between knowledge (guidelines and scientific literature) and clinical practice in the management of persistent and breakthrough pain. Promote data to the medical community through the media to bring public attention to the under diagnosis and under treatment of BTP, possibly to be followed by a publication in a medium reaching the medical community.

- **Breakthrough Awards**

Establish an awards program through a grant to a third party to recognize role models in addressing breakthrough pain. Provide platform for awardees to speak about BTP to colleagues, including hosting a Cephalon-sponsored reception at medical meeting.

- **Speaker Slide Kit "Put the Brakes on BTP"**

Develop speaker kit/video tailored to presentations to patients/caregivers. Distribute to active community speakers to enhance their discussion of BTP and treatment options.

- **Pain Tracker Evaluation**

Work with APF and CancerCare to create evidence-based support for utility of APF Pain Tracker. Convert results of study into (1) clinician's guide to using Pain Tracker with patients and (2) medical meeting abstract.

- **BTP Communications CE Program**

Develop CE program around education/communication pieces being developed through APF to be held at 2004 ONS meeting.

*Consensus Building*

- **BTP Roundtable**

Convene leaders from the pain, oncology, and patient advocacy communities under the auspices of a pain-focused professional society and a patient advocacy group. Develop consensus statement regarding what is required to improve assessment and management of BTP. Disseminate call to action to groups' membership and promote messages to media.

*Relationships with Third Parties and Key Opinion Leaders*

- **Constituency Group Support / Opportunistic Initiatives**

Provide unrestricted grants to advocacy/professional societies to conduct educational activities/events that support BTP assessment and treatment messages.

- **Nurses Advisory Board**

Seek counsel for and participation in selected activities supported under the PR plan. Coordinate meeting to identify continuing needs of the professional and consumer communities and set program directions for future activities.

- **Professional Meetings**

Interact with thought leaders at key professional society meetings to maintain Cephalon's position as a player and partner, and increase attention on BTP and ACTIQ. Host targeted events.

*Media Relations*

- **News Bureau**

Broaden public and professional understanding of BTP and ACTIQ messages through various tactics, such as: letters-to-the-editor from thought leaders in response to misleading journal articles; packaged radio and print features on BTP; radio interviews; patient-authored articles for newsletters and web sites; BTP web chats; etc.

**APPENDIX**

- 1. 2003 ACTIQ Journal Advertisements**
- 2. Long-Acting Opioids and Short-Acting Pure Opioids**
- 3. Potential Competitors**
- 4. 2004 Tactical Plan by Key Marketing Strategy**
- 5. 2004 Tactical Plan Implementation Timeline**
- 6. 2004 Tactical Budget**
- 7. 2004 ACTIQ Medical Meeting Plan**
- 8. 2004 Media Plan**

## **1. 2003 ACTIQ Journal Advertisements**

#### **ACTIQ One-Page Advertisement**





## 2. Long-Acting Opioids and Short-Acting Pure Opioids

## Long Acting Opioids

Opioid	Trade Name	Generic Name	Manufacturer
Fentanyl	Duragesic	Fentanyl Transdermal System	Janssen
Oxycodone	OxyContin	Oxycodone HCl Controlled-Release	Purdue Pharma
Morphine	MSContin Oramorph Kadian Avinza	Morphine Sulfate Morphine Sulfate Morphine Sulfate Morphine Sulfate	Purdue Pharma Roxane Faulding Ligand

## Short Acting Pure Opioids

Opioid	Trade Name	Generic Name	Manufacturer
Fentanyl	ACTIQ	Oral Transmucosal Fentanyl Citrate	Cephalon
Oxycodone*	OxyIR OxyFast Roxicodone	Oxycodone HCl Immediate-Release Oxycodone HCl Immediate-Release Oxycodone HCl	Purdue Pharma Purdue Pharma Roxane
Morphine*	MSIR Roxanol	Morphine Sulfate Morphine Sulfate	Purdue Pharma Roxane
Hydromorphone*	Dilaudid	Hydromorphone HCl	Knoll/Abbott Labs

\*Generic forms of short acting morphine, oxycodone and hydromorphone also exist.

### 3. Potential Competitors

Company	Product	Phase	Comments
Aerogenics	AERx (inhaled morphine) for acute pain and BTCP	Two Phase IIb completed which demonstrated safety, efficacy and dose reproducibility comparable to IV morphine	Goal is to move development to the single-dose device to reduce size and cost of device offered to patients
Actiq/GSK	AERx (inhaled fentanyl) for acute pain and BTCP	Preclinical	
CIMA		NDA submission 4Q03 at the latest with earliest FDA approval estimate for year-end 2004	CIMA is pursuing identical claims to Actiq (for patients that are opioid tolerant); using Actiq as comparator in human trials
Dexx	Oravescent fentanyl		
	AeroLEF (pulmonary inhalation fentanyl)	Delay in initiation of Phase II program due to company financial constraints; initiation of program in 2003 depends of financial performance of the company; 2005/2006 launch planned.	Initial increase in plasma concentrations of fentanyl that mimics the rapidity normally achieved only with intravenous infusion  Sustained therapeutic plasma concentrations that mimic the longer duration of action normally associated with slow onset products
Farmavita	transmucosal fentanyl BEMA system (bioerodible mucoadhesive system) for chronic pain and BTCP	Phase II	The BEMA film is a small, semi-soft disc that adheres to the mucosa and delivers the drug as it bioerodes.
Wels	fentanyl lozenge	suspended	Rapid onset of action with a short duration; non-invasive

## 4. 2004 Tactical Plan by Key Marketing Strategy

2004 Core Tactical Areas	Key Marketing Strategies					
	Local Awareness Type	Regional Awareness Type	Limited Focus Activities	Limited Date	Global Connected	Open Long
M&S (Product Line)	X				X	X
CE Resources	X	X	X			X
CM Teleconferences	X	X				X
ESD Initiatives	X	X				
Consultant Meetings	X				X	
Consensus Meetings	X	X				X
Advisory Boards	X	X				X
Speaker Training Meetings	X	X	X			
Promotional Materials & Reprints	X	X				
Sample Requests			X			
Informational Activities	X	X				
Public Relations	X	X	X			
Information Advertising	X	X				
Publications	X	X	X	X		X
Trade Shows				X		
Market Research					X	

## 5. 2004 Tactical Plan Implementation Timeline

2004 Core Tactical Areas	Implementation Timeline											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
CEPH Events Activities	X	X	X	X	X	X	X	X	X	X	X	X
CPE Lectures	X	X	X	X	X	X	X	X	X	X	X	X
CPE Meetings				X	X	X	X	X	X	X	X	X
CEPH Newsletter				X					X		X	
Christian Meetings				X	X		X	X	X	X		
Consensus Meetings				X	X	X	X	X	X	X	X	X
CEPH Advisory Board		X	X	X	X	X	X	X	X	X	X	X
Specialized Training Meetings	X	X	X									
Promotional Materials & Reports	X	X	X	X	X	X	X	X	X	X	X	X
Sample Orientation	X	X	X	X	X	X	X	X	X	X	X	X
Convention Activities		X	X	X	X			X	X	X	X	X
CEPH TV and Newspaper	X	X	X	X	X	X	X	X	X	X	X	X
CEPH Journals Advertising	X	X	X	X	X	X	X	X	X	X	X	X
CEPH Website	X		X		X							
CEPH Logo	?	?	?	?	?	?	?	?	?	?	?	?
Media Requests	X	X	X									

**6. 2004 Tactical Budget**

<b>2004 ACTIQ Tactical Budget</b>		<b>Total</b>
Market Research	\$	1,000,000
Consultants	\$	100,000
Journal Reprints	\$	900,000
Convention	\$	700,000
Advertising/Promotional Materials	\$	7,000,000
Sample Coupons	\$	1,450,000
Public Relations	\$	2,500,000
Field Driven Speaker Programs	\$	3,700,000
Medical Education	\$	16,600,000
Corporate Contributions	\$	150,000
RMP Requirements	\$	560,000
<b>Totals</b>	<b>\$</b>	<b>34,660,000</b>

## 7. 2004 ACTIQ Medical Meeting Plan

Name, Date, & Location	Booth Size	Specialty	# of Attendees
<b>AAHPM - American Academy of Hospice and Palliative Medicine</b> January 21-25 Phoenix, AZ	20x20	Palliative Care	500
<b>AAPM - American Academy of Pain Medicine</b> March 4-6 Orlando, FL	20x20	Pain	600
<b>APS - American Pain Society</b> May 6-9 Vancouver, Canada	20x30	Pain	2,000
<b>ONS - Oncology Nursing Society</b> April 29-May 2 Anaheim, CA	20x20	Oncology	8,500
<b>ASCO - American Society of Clinical Oncology</b> June 5-8 New Orleans, LA	20x30	Oncology	22,000
<b>AAPM - American Academy of Pain Management</b> September 8-12 San Antonio, TX	20x20	Pain	1,000
<b>AAPM&amp;R - American Academy of Physical Medicine &amp; Rehabilitation</b> October 7-10 Phoenix, AZ	20x20	Pain	2,000
<b>ASA - American Society of Anesthesiology</b> October 23-27 Las Vegas, NV	20x20	Anesthesia	16,000
<b>ASTRO - American Society for Therapeutic Radiology &amp; Oncology</b> October 3-7 Atlanta, GA	20x20	Oncology	9,000
<b>ONS - Oncology Nursing Society - Institutes of Learning</b> November 5-7 Nashville, TN	20x20	Oncology	8,500

### 8. Media Plan

	Q1 2004	Q2 2004	Q3 2004	Q4 2004	
Number of insertions	168	49	42	43	34
Avg. Exposures per MD	21.1	5.76	5.13	5.49	4.74
Total Journal Investment	\$1,046,239	\$340,061	\$250,288	\$266,407	\$189,483
Estimated CMI Fee	\$67,250				
Total Investment	\$1,113,489				

	Spend	# Insertions	# Insertions	# Insertions	# Insertions	Total Insertions
		Q1	Q2	Q3	Q4	
<b>ANESTHESIOLOGY</b>						
Anesthesia & Analgesia	\$60,351	6	6	6	6	24
Anesthesiology	\$165,719	5	5	5	5	20
Anesthesiology News	\$143,782	5	4	6	4	19
<b>ONCOLOGY</b>						
Am Jrl of Oncology Review	\$88,797	2	1	2	1	6
Jrl of Clin Oncology	\$53,443	3	3	0	0	6
Oncology Net Guide	\$63,805	2	1	2	1	6
Oncology	\$39,298	2	1	0	0	3
Oncology News Int'l	\$57,218	2	2	2	2	8
Jrl of Am Med Assn-Cancer Demo	\$20,588	2	1	1	0	4
Jrl of Supportive Oncology	\$48,730	2	1	1	0	4
<b>PAIN SPECIALIST</b>						
Jrl of Pain	\$44,942	4	6	4	4	18
Jrl of Pain Symptom Mgmt	\$83,158	4	5	4	5	18
Pain Medicine	\$16,968	2	2	2	2	8
Pain Medicine News	\$97,108	4	2	4	2	12
Practical Pain Mgmt	\$52,332	4	2	4	2	12